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| U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE |   |   |                         |
| SUPPLEMENTAL INFORMATION<br>DISCLOSURE STATEMENT           |   | Docket Number:<br><b>1662/63202</b>             |                         |
| Application Number<br><b>10/781,543</b>                    | Filing Date<br><b>February 17, 2004</b> | Examiner<br><b>Unassigned</b>                   | Art Unit<br><b>1614</b> |
| Invention Title<br><b>MENTHOL SOLUTIONS OF DRUGS</b>       |   | Inventors<br><b>Moshe Flashner-Barak et al.</b> |                         |

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to **Kenyon & Kenyon LLP, deposit account 11-0600**.

☒ 1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a

counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

☐ c. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2).

☐ 3. This Information Disclosure Statement is being filed after the mailing date of a final action, Notice of Allowance or an action that otherwise closes prosecution, but before payment of the Issue Fee. Applicant(s) hereby request(s) that the Information Disclosure Statement be considered. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

☐ 4. Relevance of the non-English language reference(s) is discussed in the present specification.

☐ 5. The references were cited in office actions in counterpart foreign applications. English language version of the foreign corresponding foreign office actions and responses thereto are attached for the Examiner's information.

☐ 6. A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.

☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination of the present application.

☐ 8. This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during the examination.

☐ 9. The reference(s) was/were cited by or submitted to the Office in parent application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).

☐ 10. English-language Abstracts of the non-English language references are attached hereto.

☐ 11. Since this application was filed after June 30, 2003, copies of U.S. references are not included.

☐ 12. Other.

Respectfully submitted,

Date: 6/21/07

Craig L. Puckett  
Craig L. Puckett, Reg. No. 43,023

KENYON & KENYON LLP  
One Broadway  
New York, New York 10004  
(212) 425-7200 (telephone)  
(212) 425-5288 (facsimile)  
CUSTOMER NUMBER 26646

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number 10/781,543  
 Filing Date February 17, 2004  
 First Named Inventor Moshe Flashner-Barak et al.  
 Art Unit 1614  
 Examiner Name Unassigned  
 Attorney Docket Number 1662/63202

## **U.S. PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|------------------------|--------------------------|--|--------------------------------|--|---|
|                        |                          | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
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## **FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns,<br>Lines, Where<br>Relevant Passages<br>or Relevant Figures<br>Appear | T <sup>6</sup> |
|------------------------|--------------------------|---|--------------------------------|---|---|----------------|
|                        |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |   |   |                |
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|                        |                          |   |                                |   |   |                |

## **NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of<br>the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue<br>number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|------------------------|--------------------------|---|----------------|
|                        |                          |   |                |
|                        |                          | Alkabes et al., "Interaction of Menthol, A Skin Permeation Enhancer, With Skin Components and<br>With Drugs" <i>Pharmaceutical Research</i> , Vol. 11, No. 10, PDD7081, S-195 (1994)  |                |
|                        |                          | Kaplun et al., "Enhancement of Skin Permeation of Testosterone by the Formation of an Eutectic<br>System with Menthol" <i>Pharmaceutical Research</i> , Vol. 11, No. 10, PDD7083, S-195 (1994)  |                |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.